

STATUS OF THE CLAIMS

Claims 1, 2, 5, 6, 8, 9 and 11 were pending.

Claim 9 has been deleted.

Claims 1, 6 and 8 have been amended.

Claims 6 and 9 have been objected to.

Claim 8 has been rejected under 35 U.S.C. §112, first paragraph.

Claim 1 has been rejected under 35 U.S.C. §102(a) over Li et al.

Claims 2, 5 and 11 have been rejected under 35 U.S.C. §103(a) over Li et al.

Claims 1, 2, 5, 6, 8 and 11 are presented for consideration.

REMARKS

Reconsideration of the above-identified application as amended is requested. Claim 6 has been amended to refer to prevention of conditions or diseases associated with IGT to make the claim clear. The reference, which is the poster presented at the World Cardiology Congress (WCC) in Sydney, Australia in March of 2002, clearly shows that nateglinide effectively controls prandial glycemia. Claim 9 has been deleted and the objection to this claim has been rendered moot. Accordingly, the objection to claims 6 and 9 have been overcome and should be withdrawn.

Claim 8 has been rejected under 35 U.S.C. §112, first paragraph as the specification allegedly does not contain any test results or experimental data using the other hypoglycemic agents of claim 8. Claim 8 has been amended such that it does not refer to other hypoglycemic agents. This amendment was done solely to advance prosecution and without prejudice to claiming the deleted subject matter in one or more continuing or divisional applications. Accordingly, the rejection has been overcome and should be withdrawn.

The rejection of claim 1 under 35 U.S.C. §102(a) over Li et al. is respectfully traversed. Claim 1 has been amended to claim nateglinide as the hypoglycemic agent. Li et al. discloses metformin only as a hypoglycemic agent. Metformin has a completely different structure than nateglinide and results obtained with metformin, in 1999, cannot have been expected by the skilled artisan to be even remotely similar to results obtained with nateglinide. This is clearly the application of an obvious to try standard which has been repeatedly stated as an incorrect basis for an obviousness rejection by the Federal Circuit.

A similar argument applies to the rejection of claims 2, 5 and 11 under 35 U.S.C. §103(a) over Li et al. Assuming that metformin has been shown by Li et al. to be an effective hypoglycemic agent to control IGT in some patients, does not mean that treating IGT related conditions with nateglinide would be suggested by Li et al. to one skilled in the art, in 1999.

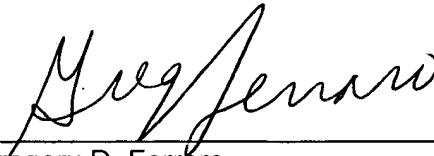
Again, metformin is a biguanide while nateglinide is an amino acid derivative. This would be a classic rejection based on hindsight. In light of these arguments, the rejections under 35 U.S.C. §102(a) and 103(a) over Li et al. have been traversed and should be withdrawn.

Attached hereto is a marked-up version of the changes made to the claims by the current amendment. The attached page is captioned **"Version with markings to show changes made."**

In view of the foregoing, Applicant submits the Application is now in condition for allowance and respectfully requests early notice to that effect.

Novartis
Corporate Intellectual Property
One Health Plaza, Building 430
East Hanover, NJ 07936-1080
(862) 778-7831

Respectfully submitted,



Gregory D. Ferraro
Attorney for Applicants
Reg. No. 36,134

Date: July 10, 2003

Version with markings to show changes made

- 1** (Once amended) A method for treating or preventing conditions and diseases associated with IGT or IFG comprising administering a hypoglycemic agent nateglinide or a pharmaceutically acceptable salt thereof to subjects in need thereof.
6. (Once amended) The method of claim 1 for the prevention conditions or diseases associated with IGT in subjects with prandial glucose excursions having 2 hour plasma glucose values between 7.8 to 11.1 mmol/L after an OGTT or casual glucose test.
8. (Once amended) The method of claim 1 wherein the hypoglycemic agent is ~~selected from group consisting of a sulfonylurea, repaglinide, nateglinide, a DPP-IV inhibitor, GLP1 and GLP1 agonist, or in in each case,~~ a pharmaceutically acceptable salt thereof.